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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,406	08/24/2001	Ben-Zion Dolitzky	1662/49603	5473

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KENYON & KENYON
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER

BERNHARDT, EMILY B

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 07/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/939,406

Applicant(s)
DOLITZKY et al.

Examiner
Emily Bernhardt

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/9/03
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 49, 51-55, 58-60, 62, 63, and 68-71 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 49, 51-53, 58-60, 62, and 68-71 is/are rejected.
- 7) ☒ Claim(s) 54, 55, and 63 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1624

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/9/03 has been entered.

The claims pending are 1-18,49,51-55,58-60,62-63 and new claims 68-71. Note that applicants have cancelled claims 19-36 in the after final amendment which has been entered as requested.

No 1449 statement is seen for the IDS newly submitted on 6/9/03. A copy is needed for consideration of the abstract provided.

The art applied in previous action is no longer relevant to claims as now amended. The search has been expanded for remaining subject matter still claimed in process and compound claims but no art has been found teaching or suggesting the Markush group of variables on instant piperazines. The following 112 rejections apply.

Art Unit: 1624

Claims 68-71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Throughout the newly presented claims "the compound of claim 49" is recited but never identified. Given the preparation of one species in these claims only one compound in claim 49 is being employed and the claims should clearly reflect this.
2. "The acid" in claim 69 lacks antecedent basis in claim 68.
3. "Piperazynyl" is a misspelling through claim 71. The "y" should be replaced by an "i".

Claims 1-18, 49, 51-53, 58-60, and 62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The how to use rejection of previous actions still remains to a large degree. As stated in the action mailed 4/17/02, the instant process and reactants, and products made are disclosed to be solely useful in ultimately making mirtazapine or its derivatives as disclosed in US 4,062,848 which is incorporated by reference on p.2 of the specification. In

Art Unit: 1624

reviewing the scope of R variables permitted in the instant process and compound claims it is noted the scope entails far more than what is ultimately taught to be within the disclosure of US'848. Compare instant R2 scope with R2 in van der Burg as well as scope of R3 with R1-containing phenyl ring in US'848. Also it is not seen how R3 other than phenyl can make the outer phenyl ring present in mirtazapine. Additionally cleavage of **all** R1 variables has not been shown can be achieved employing the hydrolysis condition shown for R1 as tosyl. Note R1 can still be phenylalkoxy in process claims . Applicants appear to dismiss the examiner's concerns and case law raised in previous actions and do not otherwise indicate how the claims as now amended overcomes the rejection. Note the following passage in In re Howarth (210 USPQ 689) regarding compliance with 35 USC 112, par.one at p.690: "Applicant's risk in leaving anything out of his application... burden rests upon applicant who chooses to rely upon general knowledge in art to render his disclosure enabling to establish that those of ordinary skill in the art can be expected to possess or know where to obtain this knowledge;"

Art Unit: 1624

Claims 54,55 and 63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication should be directed to Emily Bernhardt at telephone number (703) 308-4714.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.



EMILY BERNHARDT

PRIMARY EXAMINER

GROUP 1600